Application No. 10/715,556 Attorney Docket No.: 03806.0590-00

#### REMARKS

#### I. Status of Claims

Claims 1-8, 26-29, 31, and 32 are pending in this application. Claims 9-25 now stand cancelled. Claims 1, 4, and 8 have been amended. Claims 31 and 32 are new.

The Examiner indicates that "[i]t is unclear the status of original claims 26-28."

Office Action, page 2. The Examiner has renumbered the new claims 26 and 27, which were added in the Amendment and Submission under 37 C.F.R. §1.114 filed on January 12, 2007, as claims 29 and 30 respectively. *Id*.

Applicants respectfully submit that the original claims 26-28 were inadvertently omitted in the Amendment and Submission under 37 C.F.R. §1.114 filed on January 12, 2007, as they are clearly shown in the Amendment and Reply filed on July 25, 2006, pages 30-31. Therefore, in the present Amendment, Applicants have re-listed claims 26-28 as shown in the Amendment and Reply filed on July 25, 2006, pages 30-31.

Furthermore, in the present Amendment, claims 9-16 and 30 have been canceled without prejudice or disclaimer. Claim 1 has been amended to replace the definition of Ar in formula (I) with that recited in original claim 4. Claims 4 and 8 have also been amended to appropriately claim the present invention in view of the amendment in claim 1. New claims 31 and 32 have been added. Support for new claims 31 and 32 can be found in original claims 26 and 27, as well as in paragraphs [0154] and [0157] of the originally-filed specification. Therefore, Applicants have not introduced any new matter by these amendments, nor do these amendments raise new issues or necessitate the undertaking of any additional search of the art by the Examiner.

# II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner rejects claims 1-16 and 30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Office Action, pages 2-3. Specifically, the Examiner alleges that the limitation in claim 1 "wherein when Ar is a 9-membered bicyclic heterocycle containing one or more heteroatoms selected from N, O and S, Ar is unsubstituted" "is a new matter." *Id.* at page 3. The Examiner further alleges that "there is no written description for" that limitation. *Id.* Applicants respectfully disagree with the Examiner. However, solely to advance prosecution, that limitation in claim 1 has been deleted in the present Amendments, rendering this rejection moot. Therefore, Applicants respectfully request this rejection be withdrawn.

## III. Rejection under 35 U.S.C. § 102

The Examiner rejects claims 1-6 under 35 U.S.C. § 102(a) as being anticipated by WO 2002/022587 A1 to Nagato et al. ("Nagato"). Office Action, page 3. Specifically, the Examiner alleges that the compound, 2,3-dihydro-N-[2-(4-morpholinyl)ethyl]-3-oxo-6-phenyl-4-pyridazinecarboxamide, disclosed in Nagato anticipates the rejected claims. *Id.* Applicants respectfully disagree with the Examiner and traverse this rejection for at least the following reasons.

"A claim is anticipated only if <u>each and every element</u> as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)) (emphasis added). Further, a rejection under § 102 is proper only when the claimed subject matter is identically described or

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disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972) (emphasis added). The identical invention must be described in as complete detail as is contained in, and must be arranged as required by, the claim. M.P.E.P § 2131.

Here, the Examiner has failed to point out the specific location of the disclosure of the compound, 2,3-dihydro-N-[2-(4-morpholinyl)ethyl]-3-oxo-6-phenyl-4-pyridazinecarboxamide, in Nagato. Indeed, the inventive compounds of formula (I) disclosed in Nagato do not include this particular compound, because in formula (I) of Nagato, A2 is "a C3-8 cycloalkyl group, a C3-8 cycloalkenyl group, a 5- to 14-membered non-aromatic heterocyclic group, a C6-14 aromatic hydrocarbon cyclic group or a 5- to 14-membered aromatic heterocyclic group" (i.e., A2 is not a hydrogen). See U.S. Patent Application Publication No. 2003/0225081, which is an English-language publication of the U.S. national stage application of Nagato, page 3, paragraphs [0011] and [0012]. Therefore, this rejection is improper.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

## IV. Rejection under 35 U.S.C. § 103

The Examiner also rejects claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over WO 99/44995 to Yoshizaki et al. ("Yoshizaki"). Office Action, page 4. Specifically, the Examiner alleges that because Yoshizaki discloses a compound, i.e., 2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-pyridazinecarboxamide, "that is almost the same as [the claimed compound when in formula (I)] Ar = phenyl substituted with methoxy; A=CONH-methyl." *Id.* Further, the Examiner alleges that this particular

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compound disclosed in Yoshizaki is a homologue of the claimed compound, because "[t]he only difference between applicant's compound and the prior art compound is the presence or absence of a methyl group on the phenyl ring." *Id.* at page 5. Therefore, the Examiner concludes that it would have been obvious to modify the particular compound disclosed in Yoshizaki to arrive at the presently claimed compounds. *Id.* Applicants respectfully disagree with the Examiner and traverse this rejection for at least the following reasons.

To satisfy the initial burden of establishing a *prima facie* case of obviousness, the Examiner must first show that the prior art references teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Examiner must also show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. *In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). The Supreme Court, in the recent *KSR* case, recognized that a showing of "teaching, suggestion, or motivation" could provide helpful insight in determining whether the claimed subject matter is obvious under Section 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), slip op. at 14.

In addition, the Supreme Court mandates that "[t]o facilitate review, this analysis [of whether there was an apparent reason to modify the reference] should be made explicit." *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")).

Following the KSR decision, the Office issued a memorandum to its technology center directors on May 3, 2007, indicating that "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." (Emphasis in original.)

Here, the Examiner has failed to show that Yoshizaki teaches or suggests all the limitations of the rejected claims. The Examiner has also failed to provide any explicit reasoning to modify the teachings of Yoshizaki in an attempt to arrive at the presently claimed invention.

First, the inventive compounds of formula (I) disclosed in Yoshizaki do not include the particular compound relied on by the Examiner in support of this rejection i.e., 2,3-dihydro-6-(4-methoxyphenyl)-N-methyl-3-oxo-4-pyridazinecarboxamide, because, in formula (I) of Yoshizaki, R³ is "a lower alkyl or lower alkenyl group," (i.e., R³ is not a hydrogen). U.S. Patent No. 6,403,586 ("the '586 patent"), which is an English equivalent of Yoshizaki, col. 2, lines 33-55.

Although Yoshizaki discloses intermediate compounds of formula (4) (see the '586 patent, col. 7, lines 1-18), which may include, among many other compounds, the particular homolog compound alleged by the Examiner, the Examiner has failed to provide any explicit reasoning why the skilled artisan would pick and choose the compounds of formula (4), let alone this particular compound from all of the other compounds that are included in the compounds of formula (4).

Second, contrary to the Examiner's allegation, it would not have been obvious for one of ordinary skill in the art to modify the particular compound disclosed in Yoshizaki to arrive at the claimed compound. The particular compound disclosed in Yoshizaki has a phenyl substituted with a functional group -OCH<sub>3</sub> and serves as an intermediate. On the other hand, the claimed compound as alleged by the Examiner has a phenyl substituted with a functional group -OH (see the definition for Ar in formula (I) in the present claim 1). As one of ordinary skill in the art understands it, the functional group -OCH<sub>3</sub> is different from the functional group -OH. The Examiner has failed to provide any explicit reasoning to modify this particular intermediate of Yoshizaki in an attempt to arrive at the presently claimed invention.

In addition, "[a]n obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." M.P.E.P. § 2144.09 (quoting *In re Payne*, 606 F.2d 303, 313, 203 U.S.P.Q. 245, 254 (C.C.P.A. 1979)). The Examiner has failed to point to any evidence that the particular compound disclosed in Yoshizaki has properties similar to those of the claimed compounds.

Therefore, this rejection is improper. Applicants respectfully request that this rejection be withdrawn.

## V. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner further rejects claims 9-16 and 30 under 35 U.S.C. § 112, first paragraph, for lack of enablement for the reasons of record. Office Action, pages 6-9. Applicants respectfully disagree with the Examiner for the reasons of record. However, solely to advance the prosecution of this application, claims 9-16 and 30 have been cancelled, rendering this rejection moot. Therefore, Applicants respectfully request that this rejection be withdrawn.

#### VI. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of all pending claims.

If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the Applicants' undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filling of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

/Robert C. Stanley/ Robert C. Stanley, Reg. No. 55,830, for

By:\_\_\_\_\_ Lori-Ann Johnson Rea. No. 34,498

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